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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,998	10/08/2003	Rudi Beyaert	2676-4554.1US	7433
24247	7590	12/28/2007		
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER ROOKE, AGNES BEATA	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 12/28/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary

Application No.

10/680,998

Applicant(s)

BEYAERT ET AL.

Examiner

Agnes B. Rooke

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19,20 and 24 is/are allowed.
- 6) ☐ Claim(s) 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date Oct 1, 2007.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This FINAL office action is in response to the paper filed on 10/01/2007.

Declarations under 37 CFR 1.132 of Dr. Rudi Beyaert submitted on 10/25/2007 and 10/10/2007 are acknowledged.

Claims Disposition

Claims 19-24 are pending and under examination. Claims 1-18 are canceled.

Interview Summary

The Interview Summary is included in this instant office action.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *>"The

'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005).

In the instant invention, specifically claims 21 and 22, Applicants did not adequately disclose "a means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by said ABIN consensus sequence protein" where used in a method of screening a compound for its ability to activate or suppress ABIN dependent NF-kB inhibition, because there can be many different structures/chemicals/factors, other than disclosed TNF, IL-1, TPA, RIP, TRAF2, that can achieve the same effect and purpose in the method claimed, and the Applicants are not entitled to all of these undisclosed means of inducing activation. Therefore, the written description requirement is not satisfied.

Claim 22 is included in this invention because it does not cure the deficiency of the independent claim 21.

Claims 21 and 22 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening a compound for its ability to activate or suppress ABIN when TNF, IL-1, TPA, RIP, TRAF2 are administered to the cell line to induce activation of the NF-kB pathway, does not reasonably provide enablement for administering to the cell line any means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by ABIN consensus sequence protein

(see claim 21). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

1.) The nature of the invention: the invention is a method of screening a compound for its ability to activate or suppress ABIN.

2.) The breadth of the claims: claim 21 is very broad because it refers to any means for inducing activation of the NF-kB pathway wherein the means is inhibitable by ABIN consensus sequence protein.

3.) The predictability or unpredictability of the art: / 7.) the art is unpredictable because there can be many other different means for inducing activation of the NF-kB pathway, that are different than disclosed TNF, IL-1, TPA, RIP, TRAF2.

4.) & 5.) The amount of direction or guidance presented:/The presence or absence of working examples: the working examples are presented only in regards to TNF, IL-1, TPA, RIP, TRAF2. No guidance is provided for other means that induce activation of the NF-kB pathway that are inhibitable by ABIN consensus sequence protein.

6.) The quantity of experimentation necessary: there is a large quantity of experimentation necessary to determine what means other than TNF, IL-1, TPA, RIP, TRAF2, can be used as being administered to a cell line to induce activation of NF-kB pathway, wherein the means are inhibitable by said ABIN consensus sequence protein.

8.) Level of skill in the art: the level of skill in this art is high.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue. Claim 22 is included in this invention because it does not cure the deficiency of the independent claim 21.

Response of the Applicants to the rejection

Applicants address the rejection by stating that the claims should be address under the 35 USC 112, paragraph sixth, and that claim 21 is the only claim at issue which directly contains a means-plus-function element, and that claim 22 indirectly contains this element ("a means for inducing activation of the NF-kB pathway, wherein the means is inhabitable by said ABIN consensus sequence protein.") Further, Applicants generally discuss the prongs of the 35 USC 112, sixth paragraph, listed on page 2 of the Remarks.

Examiner responds that claims 21 and 22 were rejected under the 35 USC 112, first paragraph, and not the sixth paragraph, and were found not to satisfy the written description requirement. The rejection under 35 USC 112, sixth paragraph, was not applied in the last office action.

Further, Applicants argue that the "means" recited in claim 21 cannot be construed as covering "all of these undisclosed means of inducing activation" as the

means must be construed to cover the corresponding structure, material, or acts describe in the specification and equivalents thereof." In addition, Applicants state that examiner acknowledged that TNF, IL-2, TPA, RIP, and TRAF2 are adequately disclosed means for inducing activation of the NF-kB pathway, wherein the means is inimitable by said ABIN consensus sequence protein.

Examiner responds that the adequate disclosure was in reference to the allowed claims 19, 20, 23, and 24 only, and not to the rejected claims 21 and 22.

Further, examiner states that the outstanding rejection addressed the written description deficiencies under the 35 USC, first paragraph, and thus according to this requirement, Applicants did not satisfy the written description requirement since there can be many different structures/chemicals/factors that can achieve the same effect and purpose and result in the method claimed, and none of these factors, such as TNF, IL-2, TPA, RIP, or TRAF are listed in the rejected claims 21 and 22. Thus, the Applicants are not in possession of all of these undisclosed means of inducing activation, as currently claimed in claims 21 and 22.

Furthermore, Applicants argued that they described the means for inducing activation of NF-kB pathway in the specification to the satisfaction of claims 21 and 22.

Examiner responds that the rejected claims 21 and 22 do not point out a single compound that induces activation of the NF-kB pathway, and thus claim 21, specifically, is overly broad and do not satisfy the written description requirement, since the Applicants are not in possession of all means for inducing activation of the NF-kB dependent pathway.

In addition, Applicants state that adequate enablement exists for claims 21 and 22, as claimed 22 depends from enabled claim 21.

Examiner responds that claims 21 and 22 stand rejected, since as currently presented those claims do not specify in the claim what are the means for inducing activation of the NF-kB pathway, see detailed rejection above, and state that the rejection of the claims 21 and 22 under the 35 USC 112, first paragraph, is proper and is thus maintained.

Declarations of Dr. Rudi Beyaert

In the declaration, Dr. Beyaert stated that a person skilled in the art would know how to make and use the invention of claims 21 and 22 as TNF, IL-1, TPA, RIP, and TRAF2 are all described in the patent application to indicate their ability to perform the function of "a means for inducing activation of the NF-kB pathway, wherein means is inhibitable by an ABIN consensus sequence protein." Therefore, such means are definite as one skilled in the art will understand what materials disclosed in the patent application would perform the function of "a means for inducing activation of the NF-kB pathway, wherein the means is inhibitable by an ABIN consensus sequence protein." See Remarks on page 3.

Examiner responds that claims 21 and 22 were given the broadest reasonable interpretation and that claims 21 and 22 do not satisfy the written description requirement and also the enablement requirement. Claim 21, as currently presented, does not point out what are the means (what factors are used) for inducing activation of the NF-kB pathway, and thus one skilled in the art would not know what the factors that

induce such activation are. Further, if one skilled in the art would not know what are the factors to induce activation of the NF-kB pathway, one skilled in the art would not know how to make and how to use such invention, as currently claimed in claims 21 and 22.

Objection Maintained

Objection to Claims

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 19, 20, and 24 are allowable. Claim 23 is objected to. Claims 21 and 22 stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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